

### **REMARKS**

This is a full and timely response to the Office Action mailed September 8, 2004, filed concurrently with a one month extension of time to extend the due date for response to January 10, 2004.

No claims have been amended in this response. Thus, claims 1-19 remain pending in this application.

In view of this response, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

#### **Obviousness-Type Double Patenting Rejections**

Claims 1-5, 10-14 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/049,232 in view of Treu et al. (U.S. Patent 5,788,099).

Claims 6-9 and 15-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/049,232 in view of Treu et al. (U.S. Patent 5,788,099) and further in view of Bernstein et al. (U.S. Patent 5,366,114).

Claims 1-5, 10-14 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of copending Application No. 09/958,938 in view of Treu et al. (U.S. Patent 5,788,099) and further view of Larson et al. (U.S. Patent 6,210,646).

Claims 6-9 and 15-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over over claims 1 and 16 of copending Application No. 09/958,938 in view of Treu et al. (U.S. Patent 5,788,099) and further view of Larson et al. (U.S. Patent 6,210,646) and Bernstein et al. (U.S. Patent 5,366,114).

With regard to the provisional double patenting rejections listed above, Applicant intends to address these rejections together by filing a Rule 1.131 Declaration showing that the date of invention of the present application is prior to the effective U.S. filing date of both copending Application Nos. 09/958,938 and 10/049,232.

Applicant wishes to note that the present application has an effective U.S. filing date of December 21, 1999 and a foreign priority date of December 21, 1998. The effective

U.S. filing date of both copending Application Nos. 09/958,938 and 10/049,232 is February 16, 2001 and June 12, 2001.

Thus, upon the filing of the Rule 1.131 Declarations, these provisional double patenting rejections cannot be sustained and will be withdrawn.

For the Examiner's information, although there are some common inventors (three inventors, *i.e. Naohiko Moriyama, Ken Imai, and Tsuneo Deguchi*, for U.S. Patent Application No. 09/958,938 and two inventors, *i.e. Ken Imai, and Tsuneo Deguchi*, for U.S. Patent Application No. 10/049,232), the present and copending applications do not have the same inventive entity. Also, although there is a common assignee, *i.e. Teijin Limited*, in the present and copending applications, the present and copending applications do not have common ownership since Aksys, Limited is also an assignee of the present application (see Reel 011970, Frame 0792).

### **Rejections under 35 U.S.C. §103**

Claims 1-5, 10-14 and 19 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Treu et al. (U.S. Patent 5,788,099) in view of Larson et al. (U.S. Patent 6,210,646). Applicant respectfully traverses this rejection.

To establish a *prima facie* case of obviousness, the cited references, Treu et al. in combination with Larson et al., must teach or suggest the invention as a whole, including all the limitations of the claims. Here, in this case, the combination of Treu et al. and Larson et al. fails to teach or suggest the claimed limitations “*a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces and partially separates the membrane from the periphery of the opening whereby the medicament in the vessel falls from the vessel*” in claims 1, 10 and 19 and “*a slit extending from the inclined end into the cutter body*” in claim 14.

The Examiner stated in the action that although not disclosed in the cited references, the mechanism for vertically moving the holder toward the cutter is an obvious modification since choosing one moving part (“vertically moving holder”) over another (“a vertically moving spike”) in order to obtain a dry chemical is a matter of routine experimentation. Applicant does not agree with the Examiner in this regard.

According to the present invention, the holder is moved with respect to the cutter. This is a very important element of the claimed apparatus. If the cutter is moved upward with respect to the vessel as in the Treu et al. reference, the powder may fall on and enter into the

moving or sliding part of the cutter. Further, the sliding part may come into contact with the water. As a result, the sliding part of the cutter may easily become damaged by the powder or water. Also, Treu et al. needs a complicated means for sealing the sliding part of the cutter.

In contrast, in the present invention, the cutter is immovable, and the moving or sliding part of the holder is arranged at a higher position than the cutter. As a result, the sliding part of the holder is not affected by the powder or water. Therefore, given these advantages, choosing one moving part over another is not an obvious modification or a matter of routine experimentation.

Regarding claim 14, the claim comprises a slit extending from the inclined end into the cutter body which is not taught or suggested by Treu et al. and Larson et al. Due to this slit, the membrane for sealing the open end of the vessel is not completely removed, but a part of the membrane remains, when the cutting operation is carried out. Nevertheless, the powder medicament in the vessel can be completely discharged from the vessel. As a result, since the membrane is not removed from the vessel, the powder medicament can completely be dropped from the vessel and completely discharged therefrom. In other words, the powder medicament can be dealt within a clean state, so that the mixture of powder medicament and water having a desired density can thus be prepared. Such an element and feature is not at all described or suggested by Treu et al. and Larson et al.

Claims 2-5 and 11-13, being dependent upon claims 1 and 10, are also allowable for the reasons above. Moreover, these claims are further distinguished by the materials recited therein, particularly within the claimed combination.

For example, the mesh size is an important element for effectively mixing the power medicament with water (see claims 4 and 12). Also, claims 5 and 13 discloses a vertical moving mechanism of a holder including a feed screw for transmitting the rotational movement of the motor. Such an element is also an important element of the present invention.

Treu et al. discloses a vertical moving mechanism of a cutter including a motor for driving a belt, a member connected between a nut and a holder, and a nut. In such a configuration, the belt may deteriorate over long term use and cause a slippage of the belt. Therefore, the feed screw is better in terms of durability and accuracy.

Thus, for these reasons, withdrawal of this rejection is respectfully requested.

Claims 6-9 and 15-18 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Treu et al. (U.S. Patent 5,788,099) in view of Larson et al. (U.S. Patent

6,210,646) and further in view of Bernstein et al. (U.S. Patent 5,366,114). Applicant respectfully traverses this rejection.

As stated earlier, to establish a *prima facie* case of obviousness, the cited references, in combination, must teach or suggest the invention as a whole, including all the limitations of the claims. For the reasons noted above, the combination of Treu et al. and Larson et al. fails to teach or suggest the claimed limitations “*a mechanism for vertically moving the holder toward the cutter so that the cutting edge of the cutter pierces and partially separates the membrane from the periphery of the opening whereby the medicament in the vessel falls from the vessel*” in claim 1, and “*a slit extending from the inclined end into the cutter body*” in claim 14. Also, this deficiency is not cured by the teachings of Bernstein et al. since it is only cited to teach a piercing insert with a serrated edge.

Thus, since claims 6-9 and 15-18 are dependent on claims 1 and 14, and are further distinguished by the materials recited therein, particularly within the claimed combination., this rejection cannot be sustained and should be withdrawn.

**CONCLUSION**

For the foregoing reasons, all the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Dated: January 10, 2005

Respectfully submitted,

By 

Lee Cheng

Registration No.: 40,949

RADER, FISHMAN & GRAUER PLLC  
1233 20th Street, N.W.  
Suite 501  
Washington, DC 20036  
(202) 955-3750  
Attorneys for Applicant

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